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IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Application of: Ruddy *et al.*

Application No.: 08/852,495

Art Unit: 1644

Filed: May 7, 1997

Examiner: VanderVegt, F.P.

For: POLYMORPHISMS IN THE REGION
OF THE HUMAN
HEMOCHROMATOSIS GENE

Attorney Docket No.:
8907-057-999
(formerly 17957-000110)

**RESPONSE TO RESTRICTION REQUIREMENT AND REQUEST FOR
RECONSIDERATION UNDER 37 C.F.R. § 1.143**

Assistant Commissioner for Patents
Washington, D.C. 20231

Sir:

In response to the Restriction Requirement dated March 27, 1998 (Paper No. 7), please consider the following traversal and provisional election.

REMARKS

The Examiner has divided the pending claims into 7 groups and has required an election of one group for prosecution in the instant application. In order to be fully responsive, Applicants hereby provisionally elect with traverse Group I defined by the Examiner as encompassing Claims 1-3 and 26. However, the Applicants request reconsideration under 37 C.F.R. § 1.143 and withdrawal of the restriction requirement between Groups I, II, III, and VI for the reasons set forth below.

According to the Examiner, Groups I and II are "unrelated" pursuant to MPEP §§ 806.04 and 808.01. The Applicants respectfully disagree.

MPEP § 806.04 provides that "[t]wo different combinations, not disclosed as capable of use together, having different modes of operation, different functions or different effects are independent" and therefore subject to restriction. Under MPEP § 808.01, the finding of independent inventions depends on "the disclosure of the particular application under consideration". Examples of independent inventions are an "article of apparel such as a shoe, and a locomotive bearing", or a "process of painting a house and a process of boring a well", *see* MPEP § 806.04.

Claims 1-3 and 26 of Group I recite an "oligonucleotide comprising at least 8 to about 100 consecutive bases" that "include[] at least one polymorphic site of Table 1." Claims 4 and 27 of

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Group II recite an "oligonucleotide pair selected from the sequence of Figure 1 or Figure 2 or its complement for amplification of a polymorphic site of Table 1." However, oligonucleotides described in claims of Group I can be used as oligonucleotides as described in claims of Group II. Nowhere do the claims of Group II recite a requirement that "the oligonucleotide pairs of Group II are sequences which may not contain polymorphisms themselves," as asserted by the Examiner (see paper No. 7, p. 3). For example, an oligonucleotide containing the polymorphism at base location No. 6047 (see table 1) and an oligonucleotide containing the polymorphism at base location No. 6643 (see table 1) are both useful for "the purpose of amplifying the sequence containing the polymorphism" (paper No. 7, p. 3) at base location No. 6231 (see table 1).

Therefore, the inventions of Groups I and II are "disclosed as capable of use together", see MPEP § 806.04 (emphasis added), and the requirement for restriction regarding Groups I and II should be withdrawn.

According to the Examiner, Groups I and III are "unrelated" pursuant to MPEP §§ 806.04 and 808.01. The Applicants respectfully disagree.

The Examiner's assertion that "the nucleic acid sequences of Group III are larger segments which not only contain polymorphisms, but may encode entire or multiple gene products" (see paper No. 7, p. 3), only states the claims of Groups I and III do not cover identical subject matter, yet, the pertinent inquiry is whether they are different like, for example, a shoe and a locomotive bearing. Claims 1-3 and 26 recite, for example, an "oligonucleotide comprising ... about 100 consecutive bases" with "at least one polymorphic site of Table 1." Claims 5-11 recite, for example, an "isolated nucleic acid molecule comprising about 100 consecutive bases" with "at least one polymorphic site of Table 1."

Thus, the inventions described in Groups I and III are "capable of use together", see MPEP § 806.04, and the requirement for restriction regarding Groups I and III should be withdrawn.

According to the Examiner, Groups I, II and VI are "related as products and processes of use" pursuant to MPEP §§ 806.05(h). The Applicants respectfully disagree.

According to MPEP § 806.05(h), claims for a product and a process of using the product are only distinct if either one of two criteria is fulfilled. One, "the process for using as claimed can be practiced with another *materially* different product". Two, "the product as claimed can be used in a *materially* different process." MPEP § 806.05(h) (emphasis added).

Claims of Group I recite an "oligonucleotide comprising at least 8 to about 100 consecutive bases", and claims of Group II recite an "oligonucleotide pair". Claims of Group VI

recite a "method to determine the presence or absence of the common hereditary hemochromatosis (HH) gene mutation in an individual".

According to the Examiner, "the nucleic acid-based assay of [sic] Group VI is not strictly dependent upon the oligonucleotide pairs of Group II or [upon] measuring annealing of an oligonucleotide sequence containing a particular mutation of Group I, but can be performed by any method available to the skilled artisan for probing for specific nucleic acid sequences." (Paper No. 7, p. 4.) However, the pertinent inquiry under MPEP § 806.05(h) is whether the methods recited in Group VI "can be practiced with another materially different *product*" (emphasis added), and not whether they can be practiced with another materially different "method". The Examiner did not give an example of a "materially different product" and the Applicants respectfully submit that the "burden is on the examiner to provide an example", MPEP § 806.05(h). Thus, the Applicants submit that the first criterion of MPEP § 806.05(h) is not fulfilled.

The second criterion is also not fulfilled and the Examiner has not set forth an example of "a *materially* different process", emphasis added, in which an "oligonucleotide" as described in Group I and II "can be used". Applicants respectfully submit that methods that an "oligonucleotide" as described in claims of Group I and II can be used in are not materially different from a method as described in claims of Group VI.

For the foregoing reasons, the Applicants respectfully request that all claims of Groups I, II, III, and VI be combined in one group for immediate prosecution. Applicants submit that it will make a search of Group I highly applicable to Groups II, III, and VI.

Respectfully submitted,

Date August 7, 1998

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